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| Fees pursuant to the Consolidated Appropri | | Application Number | 10/665,518 | | |
| FEE TRANS | MITTAL | Filing Date | September 22, 2003 | | |
| | | First Named Inventor | Stamm | | |
| For FY 20 | סטו | Examiner Name | Sheikh | | |
| Applicant claims small entity statu | s. See 37 CFR 1.27 | Art Unit | 1615 | | |
| TOTAL AMOUNT OF PAYMENT | (\$) 180.00 | Attorney Docket No. | 31672-224620 | | |
| METHOD OF PAYMENT (check all that apply) | | | | | |
| Check Credit Card | Money Order Non | Other (please ide | entify): | | |

| | | Examiner Name | Sneikn | | |
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| Applicant claims small entity sta | tus. See 37 CFR 1.27 | Art Unit | 1615 | | |
| TOTAL AMOUNT OF PAYMENT | (\$) 180.00 | Attorney Docket No. | 31672-22462 | 0 | |
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| tee(s) under 37 CFR | | | | | |
| FEE CALCULATION (All the fo | | n filing or may be sub | ject to a surch | arge.) | _ |
| 1. BASIC FILING, SEARCH, AND E | | ARCH FEES EXAMI | NATION FEES | | |
| | Small Entity | Small Entity | Small Entity | | |
| Application Type Fee (\$ | | | | Fees Paid (\$) | |
| Utility 300 | 150 500 | 250 200 | 100 | | - |
| Design 200 | 100 100 | 50 130 | 65 | | - |
| Plant 200 | 100 300 | 150 160 | 80 | | - |
| Reissue 300 | 150 500 | 250 600 | 300 | | - |
| Provisional 200 | 100 0 | 0 0 | 0 | C | <u>.</u> |
| 2. EXCESS CLAIM FEES Fee Description | | | | Small Entity Fee (\$) Fee (\$) | ¥ |
| Each claim over 20 (including Reiss | sues) | | | 50 25 | |
| Each independent claim over 3 (incl | uding Reissues) | | | 200 100 | |
| Multiple dependent claims | | | | 360 180 | |
| Extra | For IA | ره/ است ده/ است | | | |
| Total Claims - 20 or HP | | | ultiple Depende ee (\$) <u>F</u> | ent Claims Fee Paid (\$) | |
| HP = highest number of total claims paid f | | <u></u> | <u> </u> | ee raid (v) | |
| Indep. Extra | | | | | |
| <u>Claims</u> <u>Claims</u> | Fee (\$) Fee P | aid (\$) | | | |
| - 3 or HP = HP = highest number of total claims paid f | or, if greater than 3. | | | | |
| 3. APPLICATION SIZE FEE | , • | | | | |
| If the specification and drawings e | xceed 100 sheets of paper | (excluding electronically | filed sequence or | computer | |
| listings under 37 CFR 1.52(e)), | | | entity) for each a | dditional 50 | |
| sheets or fraction thereof. See 3 | , | • • | | F D-14 (A) | |
| <u>Total Sheets</u> <u>Extra Sheets</u> | | Iditional 50 or fraction thered (round up to a whole number) | | Fee Paid (\$) | |
| 4. OTHER FEE(S) | _ /30 | (round up to a whole number) | ` | Fees Paid (\$) | |
| Non-English Specification, \$13 | 0 fee (no small entity disc | ount) | | recording (4) | |
| Other (e.g., late filing | ` , | 4 1 | | | ı |
| surcharge): | X Information Dis | syre Statement fee | | \$180.00 | |
| SUBMITTED BY | | \nearrow | | | = |
| Signature // // | NUX / XX | Registration No. 38,898 | Telephone | | _ |

May 8, 2006 Edward D. Grieff Name (Print/Type) Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Stamm et al

Application No. 10/665,518

Group Art Unit: 1615

Filed: September 22, 2003

Examiner: Sheikh

For: Capsules Containing Fenofibrate Compositions

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Information Disclosure Statement

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the Non Patent Literature Documents and the Foreign Patent Documents is attached hereto.

Applicants direct the Examiner's attention to:

- (a) Cite No. 1 on PTO-1449 Form No. 1 of 9, the dissolution profile on page
 12 at Table VII in Laboratoires Fournier's undated document entitled
 "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions
 Development Studies, Dissolution Test Specification Recommendations."
- (b) Cite No. 24 on PTO-1449 Form 3 of 9, the Declaration under 37 CFR § 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.
- (c) On PTO-1449 Form 5 of 9, the Declaration under 37 CFR § 1.132 by
 Pascale Blouquin with attached Exhibits 1-5 filed in US Application No.
 09/899,026 on March 7, 2005; Laboratoires Fournier's Lab Notebook No.
 1 from 18 February 1997 to 15 May 1997; Laboratoires Fournier's Lab
 Notebook No. 2 from 16 May 1997 to 30 July 1997.

 189.09 DA
- (d) In re TriCor Indirect Purchaser Antitrust Litigation, District of Delaware, Civil Action No. 05-360.
- (e) CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al, District of Delaware, 1:05-cv-00605-KAJ.

Information Disclosure Statement Page 2 of 2

(f) Walgreen Co. et al v. Abbott Laboratories et al, District of Delaware,

1:05-cv-00404-KAJ.

(g) Pacificare Health Systems, Inc. v. Abbott Laboratories et al, District of

Delaware, 1:05-cv-00591-KAJ.

(h) Painters District Council No. 30 Health and Welfare Fund et al v. Abbott

Laboratories et al, District of Delaware, 1:05-cv-00360-KAJ.

(i) Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories et al,

District of Delaware, 1:05-cv-00340-KAJ;

(j) Paul T. Tegan v. Abbott Laboratories et al, Central District of California,

2:05-cv-05410-GAF-AJW.

The submission of this Information Disclosure Statement does not represent that a search

has been made and does not constitute an admission that the listed documents, oppositions and/or

litigations are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being filed after the mailing date of a first

office action on the merits, but before a final office action or a notice of allowance. Accordingly,

the Commissioner is authorized to charge the fee of \$180 to Deposit Account No. 22-0261. The

Commissioner is authorized to charge any other necessary fees or credit any overpayments to

Deposit Account No. 22-0261.

Applicants respectfully request that the PTO return an initialed copy of the PTO-1449

Form with the next communication from the Office.

Respectfully submitted,

Edward D. Grieff

Registration No. 38.8

Date: May 8, 2006

Venable LLP

575 7th Street, NW

Washington, DC 20004

Phone: 202-344-4382 Fax: 202-344-8300

| Substitute for form | 1440/RTO | Complete if Known | | |
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| Substitute for form | 1445/F10 | Application Number | 10/665.518 | |
| INICODA | ATION DISCLOSURE | Filing Date | September 22, 2003 | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | First Named Inventor | Stamm | |
| | | Art Unit | 1615 | |
| | | Examiner Name | Sheikh | |
| Sheet 6 | of 9 | Attorney Docket Number | 224620 | |

Sheet 6

| Examiner | Cite | Document Number | Publication Date | Name of Patentee or | Pages, Columns, Lines, Where |
|----------|------|---|------------------|-----------------------------|---|
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| Examiner Cite Initials* No. | Cite No.1 | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | | |
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| 300 | salute for form 1443/FTO | Application Number | 10/665,518 | |
| 18 | FORMATION DISCLOSURE | Filing Date | September 22, 2003 | |
| | FORMATION DISCLOSURE | First Named Inventor | Stamm | |
| S | TATEMENT BY APPLICANT | Art Unit | 1615 | |
| (Use as many sheets as necessary) | | Examiner Name | Sheikh | |
| Sheet | 7 of 9 | Attorney Docket Number | 224620 | |

| Examiner Initials* | Cite No.1 | Document Number Number-Kind Code ^{2 (# known)} | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| Examiner Initials* | Cite No.1 | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | |
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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| Application Number | 10/605,518 | | |
| Filing Date | September 22, 2003 | - | |
| First Named Inventor | Stamm | | |
| Art Unit | 1615 | | |
| Examiner Name | Sheikh | | |
| Attorney Docket Number | 324620 | | |

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|------------------------|--|---|--|--|----------------|--|--|
| Examiner Initials* | Cite Document Number Publication Date Name of Patentee or Pages, Column No. Applicant of Cited Document Relevant Passa | | | | | | |
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Application Number

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September 22, 2003

First Named Inventor

Stamm

Art Unit

1615

Examiner Name

Sheikh

Attorney Docket Number

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| Examiner Initials* | Cite No.1 | 'Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevan | | |
| | | Number-Kind Code ^{2 (# known)} | | | Figures Appear | | |
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| | ļ | Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>) | MM-DD-YYYY | | Or Relevant Figures Appear | T⁵ |
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PTO/SB/08B (07-05)
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| Superi | TE FOR FORM 1449/P1O | | | Application Number | 10 | 665,518 | |
| INF | ORMATION | DIS | CLOSURE | Filing Date | September 22, 2003 | | |
| STATEMENT BY APPLICANT | | | First Named Inventor | Stamm | | | |
| | ata- a- manusha | | | Art Unit | 1615 | | |
| (Use as many sheets as necessary) | | | Examiner Name | sh į | | | |
| Sheet | 1 | of | 9 | Attorney Docket Number | 26 | 14620 | |

| | ; | NON PATENT LITERATURE DOCUMENTS | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| | 1 | Laboratoires Fournier undated document entitled "Fenofibrate Tablets 54-160 mg Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations" | |
| | 2 | "Second Amended Answer, Affirmative Defenses, and Counterclaims" filed by Teva on 7-29-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc. DE, CA No. 02-1512. | |
| | 3 | "First Amended Counterclaims" filed by Impax on 9-23-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | . 4 | "Amended Complaint" filed by CVS Pharmacy et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| • | 5 | "Amended Complaint" filed by Walgreen Co. et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 6 | "Amended Complaint" filed by Painters' District Council No. 30 et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 7 | "Amended Complaint" filed by Louisiana Wholesale Drug Co. et al on 10-3-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 8 | "Defendant's Responses to Plaintiffs Interrogatories" filed by Impax on 8-6-2003 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | . 9 | "Amended Answer" filed by Impax on 1-4-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | 10 | "Reply Memorandum" filed by Impax on 2-25-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |

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| Examiner | •, | Date | |
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| 3005000 | 18 101 101111 1449/F1O | | | Application Number | 10/665,5/8 | | |
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| STATEMENT BY APPLICANT | | | | First Named Inventor | Stamm | | |
| | ## | 4 | | Art Unit | 1615 | | |
| | (Use as many sh | eets as n | ecessary) | Examiner Name | Sheikh | | |
| Sheet | 2 | of | 9 | Attorney Docket Number | 224620 | | |

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| | 11 | "Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | 12 | "Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-23-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512. | |
| | 13 | "Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-10-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512. | |
| | 14 | "Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512. | |
| | 15 | Opposition to European Patent No. 1 273 293 filed 9-2-2005 by Ethypharm (French Language Docuement). | |
| | 16 | Opposition to Israel Patent No. 130790 filed 5-4-2005 by Teva; and Remarks in Response to Oppostion filed on 9-23-2005 (English language translations). | ✓ |
| | 17 | Munoz et al, Atherosclerosis, 110(Suppl.):S45-S48 (1994). | |
| | 18 | Pharmaceutical Pelletization Technology, Marcel Dekker, Inc., Volume 37, pages 1-13; 160-161; and 234-235 (1989). | |
| | 19 | Modern Pharmaceutics, Third Edition, Marcel Dekker, Inc., apges 131-133 and 335-356 (1996). | |
| | 20 | Pharmaceutical Dosage Forms, Tablets, Second Edition, Marcel Dekker, Inc., pages 5-28; 88-107; 133; 142; 160-165; and 260-267 (1989). | |

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| | (Use as many sne | eets as n | ecessary) | Examiner Name | Sheikh | | | |
| Sheet | 3 | of | 9 | Attorney Docket Number | 224 | 1620 | | |

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| | 21 | Shepherd Atherosclerosis, 110(Suppl.)S55-S63 (1994). | |
| | 22 | Adkins et al, Drugs, 54(4):615-633 (October 1997). | |
| · . | 23 | Letter from Teva/Novopharm to Fournier Pharma Inc. regarding Invalidity and Ambiguity of Canadian Patent Nos. 2,219,475 and 2,372,576 (pages 1-15)(September 19, 2005). | |
| | 24 | Declaration under 37 CFR 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005. | |
| | 25 | Pharmaceutical Pelletization Technology, Ghebre-Sallassie, Ed., Marcel Dekker, Inc., New York, Chapters 7 and 10 (1989). | |
| | 26 | Handbook of Pharmaceutical Excipients, 2nd Ed., pages 48-87, 141-144, 229-232, 252-261, 280-282, 392-401, 424-427, 448-450, 462-469, 491-493 (1994). | |
| | 27 | Remington's Pharmaceutical Sciences, 18th Ed., pages 1633-1665 (1985). | |
| | 28 | European Pharmacopoeia, 3rd Ed., pages xiii-xvii and 127-131 (1996). | |
| | 29 | The United States Pharmacopoeia, Vol. 23, pages liv-lvi, 1791-1793, 1924-1938 (1994). | |
| | 30 | CRC Handbook of Chemistry & Physics, 73rd Ed., Chapter 15, page 32 (1992). | |

| Examiner | | Date | |
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| | (Ose as many sne | er2 62 i | iecessary) | Examiner Name | Sheikh | | | | |
| Sheet | 4 | of | 9 | Attorney Docket Number | 22 | 462 | 0 | | |

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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| | 31 | Suzuki et al, Chem. Pharm. Bull., 49(4):373-378 (2001). | |
| | 32 | Shah et al, International Journal of Pharmaceutics, 125:99-106 (1995). | |
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| | 35 | Kuchiki et al, "Stable Solid Dispersion System Against Humidity," Yakuzaigaku, 44(1):31-37 (1984). | |
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| | 37 | Boullay, "Microgrinding and Dissolution," S.T.P. Pharma, 1(4):296-299 (1985). (French-language document and English language translation). | 1 |
| | 38 | International Dictionary of Medicine and Biology, Volume 2, page 1774, John Wiley & Sons, Inc. (1986). | |
| | 39 | Opposition to EP 952 829 by Winthrop Arzneimitel GmbH filed March 31, 2005. | |
| | 40 | Opposition to EP 952 829 by Laboratoires SMB SA filed April 11, 2005. | |

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| | (Use as many sne | cro 92 II | •••••••• | Examiner Name | Sheikh | | |
| Sheet | 5 | of | 9 | Attorney Docket Number | 22 | 1620 | |

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| | 41 | Papers filed on April 15, 2005, by Ethypharm in Response to Patent Proprietor's Statement of Opposition to EP 952 829. | |
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| - 1 | 43 | Handbook of Pharmaceutical Excipients, Second Edition, pages 392-399 (1994). | |
| | 44 | Complaint, US District Court for the District of Delaware, Civil Action No. 04-350, Reliant Pharmaceuticals v. Abbott Laboratories et al (June 1, 2004). | |
| | | Declaration under 37 CFR 1.132 by Pascale Bloquin filed in US Application No. 09/899,026 on March 7, 2005. | • |
| | | Laboratoires Fournier's Lab Notebook No. 1 (attached as Exhibit 1 (French) and Exhibit 3 (English translation) to the 132 Declaration by Bloquin). | ✓ |
| | | Laboratoires Fournier's Lab Notebook No. 2 (attaches as Exhibit 2 (French) and Exhibit 4 (English translation) to the 132 Declaration by Bloquin). | 1 |
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